REMARKS

In response to the Official Action mailed November 5, 2007, Applicant respectfully requests reconsideration, reexamination and allowance of claims 1-3, 5, 8 and 12-24 in view of the following amendments and remarks. By this amendment, Applicant has amended claims 1, 15, 19 and 24 to recite *coagulating ultrasound beam* instead of *ultrasound beam for coagulation* in order to more specifically point out that it is the ultrasound beam itself that coagulates tissues or vessels. Further, claim 1 was also amended in view of paragraph [0125] and Fig. 23 of the US publication and claims 15 and 19 were further amended in view of paragraph [0039] and Figs. 1 and 2 of the US publication so as to more clearly define the present invention.

The amendments to claims 2 and 16, further, overcome the section 112 objections. Claims 4, 6-7 and 9-11 have been cancelled without prejudice to advance the prosecution of the present Application.

Preliminary Explanation

As a preliminary, it seems that the Office is not clear on difference between the two different kinds of ultrasound technologies that are used in the therapeutic field. For this reason some of the rejections made are not on point. Applicant in order to clarify will try to explain the differences.

A first technology - to which relate the Davison and Farin references - consists in applying vibrations at ultrasonic frequencies to a tip or a blade which contacts the tissue to be treated. This technology may be use for cutting tissue and/or coagulating tissue. In the latter case, the vibrating tip or blade may cause coagulation of the tissue due to frictional heat resulting from the ultrasonic vibrations of the tip or blade that is brought in contact with the tissue. Heating depth depends on the tissue heat conduction characteristics and anyway is limited to tissue in contact with the vibrating tip or blade. The ultrasound frequencies involved in this first technology are in the range of some tens of KHz (see Davison, c.4, l.66 citing 55,5 kHz).

Applicant refers to this first technology as the vibrating technology.

A completely different technology – to which relate the present invention and the Lafon reference- consists in using an ultrasound transducer that emits an ultrasound beam that is directed to the tissue or vessel to be coagulated and propagates away from the ultrasound transducer. Coagulation occurs as a result of the ultrasound energy delivered by the beam and absorbed in the tissue. Heating depth depends on the ultrasound absorption characteristics of the tissue and is not limited to tissue in contact with the ultrasound transducer. Unlike the vibrating technology, the ultrasound frequencies involved in this second technology are in the range of some MHz (See US publication of the application, [0040] citing 8-20 MHz and [0127] citing 10 MHz, see also Lafon, c.4, l.51-52 citing 5-10 MHz and Chopra, c.6, l.64 citing 2-10 MHz).

Applicant refer to this second technology as the beam technology.

With this explanation, then, Applicant now provides a discussion and response to the points made in the present Office Action..

A) Objection under 35 USC §102 against claims 13 and 14

The Office Action has rejected claims 13-14 under 35 USC § 102 (b) as being anticipated by Davison et al (US Patent No. 5,324,299). The objection for lack of novelty raised against claim 13 on the basis of Davison is not correct.

• Claim 13 specifically recites *an ultrasound transducer for emitting a coagulating ultrasound beam*. [emphasis added]. It is clear from this wording that the ultrasound beam causes coagulation by itself, i.e. the ultrasound beam is directed to the tissue or vessel to be coagulated, coagulation occurring as a result of the ultrasound energy delivered by the beam to the tissue or vessel (see e.g. [0114] of the US publication). And the claimed scalpel blade is not involved in the coagulation that is caused by the ultrasound beam. In other words, the invention claimed in claim 13 relates to a beam technology. But Davison does not disclose this feature.

Davison discloses an ultrasonic scalpel blade for cutting and coagulating (see c.1, l.7-10). In Davison, ultrasonic energy is transmitted to the blade which in turn coagulates the tissue with which the blade is in contact (see e.g. c.1, l.11-20 about the related prior art, and c.1, l.43-53 (in particular, l.50-53) and l.58-65 about the improvement provided by Davison. See also c.4, l.64-

68). Ultrasonic energy is provided to the blade via a blade coupler (see c.3, l. 7-12 and ref. 10 in fig. 1). Coagulation in Davison is obtained in a similar way as in Okada that was discussed in reply to the previous Office action, i.e. coagulation is due to frictional heat resulting from ultrasonic vibrations conveyed to a member that contacts the tissue. (see response of Feb. 5, 2008, page 9, last paragraph – page 10, first paragraph).

In other words, Davison relates to a vibrating technology, not a beam technology.

In support of his objection, the Examiner mentions:

> *Davison et al disclose an ultrasonic scalpel blade 12, wherein an ultrasonic transducer emits ultrasonic radiation to cause the blade to vibrate for improved coagulation.* [emphasis added]

But this statement is not correct. Davison does not emit ultrasonic radiation to cause the blade to vibrate. Davison causes the blade to vibrate with help of a mechanical coupling (see blade coupler 10) for transmitting mechanical vibrations (at ultrasound frequencies) generated by the ultrasonic source to the blade. So, it is not an ultrasound beam (or ultrasonic radiations) that causes the blade to vibrate. And further, it is not an ultrasound beam directed on the tissue or vessel that coagulates the latter as is the case in the invention, but it is frictional heat resulting from ultrasonic vibrations conveyed to the blade that contacts the tissue as already mentioned above.

As a result, in Davison, coagulation is not obtained with an ultrasound beam that is directed to the tissue or vessel to be coagulated so that coagulation results from the ultrasound energy delivered by the beam to the tissue or vessel. In other words, Davison fails to disclose the claimed *coagulating ultrasound beam.*

• Further, claim 13 further recites that *said scalpel blade is movable with respect to said transducer when the ultrasound coagulation apparatus is in operation.* Davison does not disclose this feature either. Indeed, when in operation, the transducer is necessarily fixedly attached to the scalpel via blade coupler 10 in order to transmit the ultrasound vibrations to the scalpel blade. As a consequence, the invention of claim 13 is novel over Davison for this further reason.

• Applicant again reemphasizes that the beam technology and the vibrating technology are two completely different technologies as already mentioned. As a consequence, the person having ordinary skill in the art would never think of adapting an apparatus based on a vibrating technology to make of it an apparatus based on a beam technology: this does not correspond to a realistic approach.

In addition to pointing out the differences, the invention, as disclosed in claim 13, is advantageous over Davison because:
- coagulation is obtained with a coagulating ultrasound beam instead of frictional heat; and
- the scalpel blade can move with respect to the transducer.

Using a coagulating ultrasound beam allows coagulating until a given depth in a tissue while coagulating with frictional heat as does Davison only results in superficial coagulation which can be insufficient e.g. in case of important vascularization of an organ (see. e.g. in the case of partial kidney ablation discussed in [0116] of the US publication).

Further, the fact of using a coagulating ultrasound beam in combination with the fact that the scalpel blade is movable with respect to the ultrasound transducer when the ultrasound coagulation apparatus is in operation is advantageous in that it allows to first coagulate wholly a section of the tissue before cutting through this section with the scalpel blade. As a consequence, there is no risk of hemorrhaging because it makes it possible to cut through a given section of tissue after it was wholly coagulated by the ultrasound beam. On the contrary, the risk of hemorrhaging exists in Davison, in particular in the case of important vascularization of the tissue, because cutting and coagulating occur at the same time and coagulating is only superficial: as a result, it is possible that the tissue is not sufficiently coagulated to prevent hemorrhaging.

Thus, the invention of claim 13 involves also an inventive step as nothing in the cited references suggests the claimed arrangement.

B) Objection under 35 USC §103 against claims 1-12 and 15-24

The Office Action has rejected claims 1-12 and 15-24 under 35 USC § 103(a) as being unpatentable over Farin et al. (US Patent No. 5,776,092) in view of Lafon et al (US Patent No. 6,379,320). The Office Action's objection is one of a lack of inventive step in the invention based on Farin et al in view of Lafon et al. Applicant strenuously disagrees and respectfully suggests that the objection is not correct.

i) Claims 1, 15, 19 and 24 are distinguished over Farin by reciting a *coagulating ultrasound beam* on the contrary of the Examiner

• Farin et al discloses a multifunctional surgical instrument which comprises an applicator for ultrasonic surgery and an applicator for RF surgery and/or an applicator for laser surgery (see c.2, l.25-29). In Farin et al, the applicator for ultrasonic surgery is coupled to an electroacoustical transducer (see c.3, l.61-66) in order to apply ultrasound vibrations to the applicator which contacts the tissue either directly or via a tip connected to it (see c.3, l.63 – c.4, l.2). In other words, Farin et al relates again to a vibrating technology similarly to Davison, but not to a beam technology.

In sharp contrast, independent claims 1, 15, 19 and 24 each recite an ultrasound transducer for emitting a coagulating ultrasound beam. Clearly, these claims relate to the beam technology (similarly as for claim 13 discussed under item A) above).

Further, in Farin et al, the ultrasound applicator is not even used for coagulating, but for cutting while coagulating is obtained by the RF applicator (see c.1, l. 5-16 and especially l.5-8 and l.13-16 – see also the independent claims).

Applicant respectfully suggests that the inventions of claims 1, 15, 19 and 24 are distinguished over Farin et al for this first reason. Here again, Applicant draws the Office's attention to the fact that the beam technology and the vibrating technology are two completely different technologies.

As a consequence, a person having ordinary skill in the art would never think of adapting an apparatus based on a vibrating technology to make of it an apparatus based on a beam

technology: this does not correspond to a realistic approach. As such the claims rejected are not obvious. Additionally, the discussion under item A) above in support of claim 13 about the advantages of the beam technology over the vibrating technology, applies here in the same way in further support of claims 1, 15, 19 and 24.

ii) Claims 1, 15, 19 and 24 are further distinguished over Farin et al. by reciting *at least one* or *a planar transducer* as acknowledged by the Examiner

The Office Action acknowledged that Farin et al. does not teach a planar transducer, but is of the opinion that it would have been obvious for the skilled artisan to modify Farin et al. as taught in Lafon et al., which discloses a planar transducer.

Applicant respectfully suggests that this reasoning is not correct. Indeed, as mentioned, Farin et al. relates to a vibrating technology. In sharp contrast, Lafon et al. relates to a beam technology (see e.g. c.3, l.20-26). Clearly, these documents relate to two completely different types of technologies and that make use of two different types of transducers (emitting a beam vs. providing mechanical vibrations). Applicant therefore suggests that, a person having ordinary skill in the art would never think to combine these documents.

iii) Claim 1 is further distinguished over Farin by reciting *a channel [...] adapted to transmit a partial vacuum for keeping the laparoscopy probe in place on an organ when emitting the coagulating ultrasound beam to the organ with the at least one planar ultrasound transducer*

The Office Action stated about Farin et al. that *the instrument also includes a connector 13 for suction that helps keep the probe in place on an organ* (see c.4, l.29-33). However, Applicant respectfully suggests that this statement is not correct. Farin et al. does not disclose that the connector 13 for suction aims to help keeping the probe in place on an organ.

Applicant draws attention to the fact that the connector 13 itself is mounted on the handle 1 of the instrument, and not at the operative end of the instrument (where are located the ultrasound and RF applicators 3 and 6 –see fig. 1a). In other words, connector 13 is neither close to the tissue to be treated nor close to it. In fact, as clearly shown, connector 13 is used to connect the instrument to some source providing a suction effect at the operative end 3 of the instrument. The suction function is shown in detail in Fig. 7 (see also col.6, lines.28-31) in which suction occurs through tube 3 forming the ultrasound applicator.

However, Farin et al. does not disclose that said suction *helps keep the probe in place on an organ* as stated in the Office Action. In fact, Farin et al. mentions that the suction function is known as such (see col.6, lines.28-31) and is always described in combination with the rinsing function (see also col.4, lines.31-33). It results therefrom, that the suction function serves to aspirate the rinsing liquid (used to clean the treated region of the organ, i.e. notably removing cut tissue and blood). This suction function is further to be understood in view of the background section from which it results that the suction function consists in aspirating tissue that is removed with the ultrasound applicator (see col.1, lines.32-42). In other words, the suction function does not aim to keep the probe on an organ, but to aspirate rinsing liquid as well as blood and tissue removed by the cutting action of the ultrasound applicator.

Further, the operative end 3 of the ultrasound applicator is in the form of a tube (as shown in Fig. 7) through which suction occurs. As a result, Applicant respectfully suggests that it is more than doubtful that the suction effect helps keeping the probe on an organ because the suction-grip effect of the suction through operative end 3 will only apply on tissue removed by the surrounding operative end 3 of the ultrasound applicator when the ultrasound applicator is in operation. Regarding this matter, Farin et al. may be compared to the embodiment of the present invention shown in Fig. 23 and described in paragraph [0125] where the suction channel (for keeping the probe in place on the organ) surrounds the ultrasound transducer (and not the contrary as in Farin et al.). Further, no cutting effect occurs due to the coagulating ultrasound beam.

As a conclusion, Applicant respectfully notes that Farin et al. does not teach *a channel [...] adapted to transmit a partial vacuum for keeping the laparoscopy probe in place on an organ* when the ultrasound transducer is in operation. Thus claim 1 is distinguished over Farin et al. for this further reason. As a general conclusion about claim 1, Farin et al. proves to be very remote from the invention claimed in claim 1 and does contain the faintest hint for obtaining it either contemplated alone or in combination with other documents. Thus, the invention of claim 1 is believed to be patentable.

iv) Claims 15, 19 and 24 are further distinguished over Farin by reciting a *planar ultrasound transducer without a membrane*

The Office Action notes, with respect to Farin et al., that *there is no type of membrane on either the transducer or the entire instrument.* However, Applicant respectfully suggests that this statement is pointless because Farin et al. does not relate to the beam technology, as is the case of the invention, but to the vibrating technology as already mentioned.

In the cited references and the state of the art prior to the present invention, regarding the beam technology, a membrane was always used for retaining the coupling/cooling liquid; the liquid providing ultrasound coupling between the transducer and the membrane and in turn the tissues to be treated by the ultrasound beam (see discussion about Lafon et al. in the reply of the applicant of June 5, 2007 to the first Office action). Of course, this ultrasound coupling issue does not exist in the vibrating technology as there is no ultrasound beam to be coupled to the tissue in this case. That is why Applicant believes that it is pointless to refer to Farin et al. for challenging the inventiveness of this feature within the beam technology.

Further, Applicant previously explained, in reply to the June 5, 2007 Office Action, why it was not obvious to make use of a *planar ultrasound transducer without a membrane* as claimed in claims 15, 19 and 24 in view of Lafon et al. in the case of the beam technology.

v) Claims 15 and 19 are further distinguished over Farin et al. by the fact that the transducer *is mounted at the end of a cable,* that it *is powered via said cable* and that *said cable and said planar ultrasound transducer form an assembly adapted to pass in an operating channel of an/the endoscopic apparatus.*

It appears that the Office Action did not see that in claims 15 and 19 the transducer *is mounted at the end of a cable* as this is not mentioned in the Office Action in discussion of this feature. Applicant avers that Farin et al. does not teach or suggest this feature. In fact, Farin et al. does not even show the ultrasound transducer: it only shows a connector 12 for connecting the transducer, said connector being mounted on the handle 1 (see c.4, l.30-31 and Fig. 1a).

Further, in order to define more precisely their inventions, claims 15 and 19 have further been amended to specify that the invention claimed therein *is powered via said cable* and that *said cable and said planar ultrasound transducer form an assembly adapted to pass in an operating channel of an/the endoscopic apparatus*. In sharp contrast these features are taught or suggested by Farin et al.

As a conclusion about claims 15 and 19, Farin et al. is very remote from the claimed inventions and does contain the faintest hint for obtaining it either contemplated alone or in combination with other documents. Further, Applicant has already explained why Lafon et al. does not suggest the inventions claimed in claim 19 in his reply of June 5, 2007 to the first Office action. As a conclusion, the inventions of claims 15 and 19 are believed to be patentable.

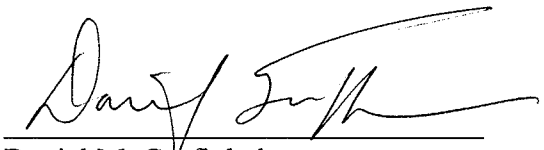
vi) Claim 19 is further distinguished over Farin by reciting *a cooling and coupling fluid circuit, with fluid inlet and outlet openings.*

The Office Action notes that the instrument disclosed in Farin et al. includes *a connector 14 for rinsing, thus also acting as a cooling and coupling fluid circuit.* Applicant respectfully suggest that this statement is not correct at least insofar Farin et al. relates to a vibrating technology and that a vibrating technology does not involve any coupling fluid. Indeed, a coupling fluid is required in the beam technology in order to ensure that the ultrasound beam reaches the tissue to be treated.

In Farin et al., the rinsing fluid aims only to removing blood and tissues that were cut by the vibrating tip of the instrument. But the rinsing fluid has absolutely no coupling function as no ultrasound beam has to be coupled to the tissue in the vibrating technology. As a consequence, Farin et al. cannot be considered to teach a cooling and coupling fluid circuit. Thus, claim 19 is believed to be patentable for this further reason.

In view of the foregoing remarks and amendments, it is believed that the subject application is now in condition for allowance, and an early Notice of Allowance is respectfully requested. Applicant encloses herewith a petition for a one month extension of time to respond to this Office Action as well as an authorization for the Commissioner to charge the fee for the petition to Applicant's attorney's deposit account (No. 23-0920). It is believed that no other fee is needed, however, should it be determined that any fees are necessary the Commissioner is hereby authorized to charge any additional fee which may be required for this application under 37 C.F.R. §§ 1.16-1.18, including but not limited to the issue fee, or credit any overpayment, to Deposit Account No. 23-0920. Further, should any petition be required with respect to this reply and amendment, the Commissioner is respectfully requested to treat this paper as the necessary petition or petitions and to charge the petition fee(s) to the above noted deposit account.

Respectfully submitted



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